REMARKS

Entry of the foregoing, and further and favorable consideration of the subject application is respectfully requested.

Claims 55-99 are pending in the present application. Claims 59, 60, 80, 81, 83, 84, 95, 96, 98, and 99 stand withdrawn from consideration. Claims 55-58, 61-79, 82, 85-94, and 97 stand rejected.

Support for the amendment to claim 86 can be found on, at least, page 8, lines 24-31. No prohibited new matter has been added.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 75, 77-79, and 86 stand rejected under 35 U.S.C. § 112, second paragraph as purportedly indefinite. The Examiner suggests that "suitable" is a relative term, rendering claims 75 and 77 (and therefore, dependent claims 78 and 79) indefinite. The Examiner rejected claim 86 as indefinite as to the meaning of "low."

Without conceding to the grounds of the rejection, and solely in an effort to expedite prosecution, the rejected language has been deleted from claims 75 and 77, rendering the rejection moot.

Without conceding to the grounds of this rejection, and solely in an effort to expedite prosecution, claim 86 now recites "wherein the plasticizing oil is selected from low molecular weight branched chain aliphatic acids and alcohols which reduce the viscosity of the carrier system," in order to further define the invention. Such functional language is appropriate. Applicants respectfully submit that the term "low" molecular weight with

respect to the plasticizing *oil* would be understood by one skilled in the art. Applicants direct the Examiner's attention to The Handbook of Pharmaceutical Excipients (A.H. Kibbe, editor, 3rd edition, 2000), of which copies of the pertinent pages are enclosed for the Examiner's convenience. Applicants point out that an example of such a plasticizing oil is given in the specification on page 8, line 31 ("fluid lanoline"). The main alcohol constituent of fluid lanoline oil is cholesterol, which has a molecular weight of 387. Based on this disclosure and the more detailed information on lanoline alcohols given in the enclosed excerpts from the Handbook of Pharmaceutical Excipients, it would be clear to one skilled in the art that the term "low" in claim 86 refers to a substance having a molecular weight of up to about 400. Thus, one skilled in the art would reasonably know the metes and bounds of the present invention. Withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 55-58, 61-79, 82, 85-94, and 97, stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Yamada *et al.* (U.S. Patent 5,362,497) in view of Wang *et al.* (U.S. Patent 4,299,828) and Cooper *et al.* (U.S. Patent 4,552,872). The Examiner argues that Yamada *et al.* disclose a transdermal therapeutic composition comprising a pharmaceutical active ingredient, a water-soluble absorption enhancer, a fat soluble absorption enhancer comprising fatty alcohol, and a lower alchol ester of aliphatic carboxylic acid. The Examiner admits that Yamada *et al.* do not expressly teach the particular formulation of the invention "which has corticosteroid as the active ingredient,

and comprising unsaturated alcohols, lower alcohol ester of fatty acid, wax, and plasticizing oil with the particular percentage, or the particular form, stick, or the method of using the same." [See Official Action, pages 3-4]. However, the Examiner suggests that Cooper *et al.* disclose unsaturated alcohols are particularly useful in topical corticosteroid compositions and the inclusion of wax for stiffness. The Examiner further believes that Wang *et al.* disclose a corticosteroid stick formulation with wax. Thus, the Examiner surmises that one of "ordinary skill in the art would be motivated to modify the composition of Yamada to make a corticosteroid topical composition employing oleyl alcohol as the fat soluble enhancer and propylene glycol as the water soluble enhancer with the particular amounts claimed herein because both are known to be useful to enhance the absorption of active ingredients...The employment of wax and plasticizer to render the final product certain properties is seen to been within the skill of artisan." [See Official Action, pages 4-5].

In order to establish *prima facie* obviousness under 35 U.S.C. § 103, the cited reference or combination of references must teach or suggest every element of the claims. Moreover, there must be motivation, outside of Applicants' disclosure, to modify or combine the cited references. See M.P.E.P. 2143 *et seq.*

Applicants assert that Yamada *et al* is *irrelevant* to the claimed invention. Applicants' invention is intended to solve the problem presented in the "Background of the Invention" section of the present application on page 1, line 13, to page 3, line 2. Namely, the claimed invention seeks to attain a satisfactory solid composition, preferably in the form of a stick. Applicants acknowledge that Yamada *et al.* disclose a transdermal composition

comprising an active ingredient, e.g., a corticosteroid, a water-soluble absorption enhancer, e.g., propylene alcohol, a fat-soluble enhancer, e.g., oleyl alcohol, and a lower alcohol, e.g., myristic acid. However, Applicants respectfully point out that the Examiner has neglected to recite a prominent feature of Yamada *et al.*: the benefit of separating the water-soluble and fat-soluble enhancers via the use of a "superabsorbing" polymer (column 2, lines 25-35). Further, Yamada *et al.* disclose a homogenized two or higher phase system where the water-soluble enhancer is absorbed in a polymer separated from the fat-soluble enhancer. The superabsorbing resin is a requisite part of the Yamada *et al.* invention. The invention of the present application relates to a single phase mixture of enhancers, an active ingredient and a defined lipid composition to form a stick. The Yamada *et al.* publication, in seeking to keep the enhancers separated from each other, thus *teaches away* from the present invention. Formulations according to the present invention must not contain water while the Yamada *et al.* teach the use of water and emulsifiers to create a multiphase system. Applicants further submit that the invention of Yamada *et al.* is intended for transdermal delivery of a therapeutic composition in order to produce the intended *systemic* effect (column 1, lines 19-23), while Applicants' invention is directed toward the *local delivery* of the therapeutic ingredient *to the skin*.

Applicants maintain their earlier argument that Cooper *et al.* also teach away from the present invention. The Examiner's attention is directed to column 10, lines 35-54, wherein Cooper *et al.* specifically state that the use of hydrocarbons should be avoided or limited to not more than 10%, preferably not more than 5%. Applicants have discovered satisfactory delivery of the active ingredient in a composition that contradicts the teachings

of Cooper *et al.* Cooper *et al.* also state that fatty alcohols should be avoided due to lowered absorption of the active ingredient and that the use of oils should preferably be limited to less than 0.5% (column 10, line 55, to column 11, lines 17), which is also in direct contrast to the claimed invention.

Applicants have clearly demonstrated that both Yamada *et al.* and Cooper *et al.* teach away from, rather than suggest, the present invention. Applicants strongly disagree that the combination of the Yamada *et al.* and Cooper *et al.* publications (in further combination with Wang *et al.*) would have thus motivated one skilled in the art to arrive at the present invention. Accordingly, Applicants submit that the present invention cannot be *prima facie* obvious over Yamada *et al.* in view of Wang *et al.* and Cooper *et al.* Withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions concerning this paper, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,
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Attachment to REPLY & AMENDMENT dated July 11, 2001

Marked-up Claims 75, 77, and 86

75. (Amended) A composition as claimed in Claim 74, [which is suitable] for topical application to the skin of a mammal, and possesses a viscosity that is adapted for such application.

77. A method of prophylactic or therapeutic treatment of a dermatological condition comprising topically applying a prophylactically or therapeutically effective amount of an active agent containing solid composition according to Claim 55, wherein the active agent is [suitable] an agent for treatment or prophylaxis of a dermatological condition.

86. (Amended) A composition as claimed in Claim 55, wherein the plasticizing oil is selected from low molecular weight branched chain aliphatic acids and alcohols which reduce the viscosity of the carrier system.